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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,214

04/21/2006

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EXAMINER

SASAKI, SHOGO

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,214	<b>Applicant(s)</b> OHMAN ET AL.	
	<b>Examiner</b> Shogo Sasaki	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,5 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-14,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/2009</u> .                                               | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Amendments to the claims are acknowledged.

#### ***Claim Interpretations***

2. Regarding claim 2, the limitation "each flow path is connected to a sink of said two or more sinks" was interpreted to mean that the multiple flow paths are each connected to corresponding sinks; instead of the multiple flow paths being connected to one of the multiple sinks and other sinks have no connections to any flow path.
3. Regarding claim 9, it is suggested to positively set forth "a sub-section within said at least one sink" as part of the claimed subject matter. "Said at least one sink is adapted for division into subsection" was interpreted to mean at least one sink has an area, in which any portion thereof can be considered a subsection.
4. Regarding claims 1, 2, 4, 6-10 and 14, recitations [claim 1] "said projections configured to achieve a capillary flow and thereby support or control the flow rate of said liquid sample through said transport or incubation zone;" [claim 2] "said device adapted to perform multiple analyses on one liquid sample;" [claims 4 and 6-10 ] entire recitations; and [claim 14] "to prevent back flow of said liquid sample," which are directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 6-14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Regnier et al. (US 6156273).

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Regarding claims 1, 2, 4, 6-14, 19 and 20, Regnier et al. disclose a device for handling a liquid sample comprising (column 3, line 36-column 12, line 51):

- at least one flow path (Fig. 6: 107, 108, 109, 114, 116);
- at least one zone (Fig. 6: 99, 118);
- a transport zone (Fig. 6: 112);
- at least one sink (Fig. 6: 100) comprising an area having projections (Fig. 1B, 14; or Fig. 2A-2F: These are present on the 100 side as well.) substantially vertical to its surface, said projections configured to achieve a capillary flow (The fluid flow in the direction of the arrow 110. Therefore the side 102 must be the source and the side 100 will have to be the sink. The flow paths with or defined by projections of Regnier et al. are capable of causing a capillary flow.);
- wherein said at least one flow path is two or more flow paths (Fig. 6: 107, 108, 109, 114, 116); said at least one sink is two or more sinks (The side 100 in Fig. 6 include channels 104, which is equivalent to 12 on the side 102 (Fig. 1A; column 5, line 61; and column 11, line 31). Any configuration/interconnections of the channel 104 may effectively form variety of sinks.); each flow path is connected to a sink of said two or more sinks (The flow path 109 are connected to corresponding portions of sink having square cross-sectional projections.);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 6: 107, 108, 109, 114, 116);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 1 A and 6: The flow path 107-108-109 provides 3 different types of polygonal vertical projections.);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 1 A and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections.);

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- a design feature (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.);
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.); and
- wherein said projections have heights (Fig. 1A).

7. Claims 1, 2, 4, 6-14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhullar et al. (US 6451264).

Regarding claims 1, 2, 4, 6-14, 19 and 20, Bhullar et al. disclose a device for handling a liquid sample comprising (abstract):

- at least one flow path (Fig. 1: 16, 18, 24, 26, 28);
- at least one zone (Any area in said fluid pathways may be considered a zone.);
- a transport zone (Any portion of said fluid pathways may be considered transport zones.);
- at least one sink (Fig. 1: 20) comprising an area having projections (Fig. 5, 37, 39; and column 4, lines 57-63) substantially vertical to its surface (These leads are formed via etching/lithography, thus they must protrude from the bottom surface of the site 20.); said projections configured to achieve a capillary flow (The fluid flows to the testing site 20 (column 4, lines 8-13). Therefore the inlet 14 must be the source and the site 20 will have to be the sink. The flow paths with or defined by projections of Bhullar et al. are capable of causing a capillary flow.);
- wherein said at least one flow path is two or more flow paths (Fig. 1: 16, 24, 26, 28); said at least one sink is two or more sinks (Fig. 1: 20); each flow path is connected to a sink of said two or more sinks (Fig. 1);

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- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 1: 16, 24, 26, 28; column 4, lines 22-26);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 2 and 3; column 5, lines 1-39);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 2 and 3; column 5, lines 1-39);
- a design feature (Fig. 2 and 3; column 5, lines 1-39); and
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 2 and 3; column 5, lines 1-39); and
- wherein said projections have heights (Fig. 2).

8. Claims 1, 6-14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohman et al. (WO 3103835).

Regarding claims 1, 6-14, 19 and 20, Ohman et al. et al. disclose a device for handling a liquid sample comprising; and a method of using the same (abstract):

- at least one flow path (Fig. 10);
- at least one zone (Fig. 10, zones 1-3);
- a transport zone (Any zone in said path way may be considered a transport zone, since the fluid flows through them.);
- at least one sink (Fig. 9, The exit with pad 10; and page 11, lines 8-17) comprising an area having projections (Fig. 9, The exit where 10 is laid on effectively becomes the flow sink as disclosed; and it has vertical projections in that particular area; page 11, lines 1-7) substantially vertical to its surface; said projections configured to achieve a capillary flow (The flow paths with or defined by projections of Ohman et al. are capable of causing a capillary flow.);

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- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 11 and 12: 1);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 11 and 12: 1);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (page 5, lines 11-13);
- a design feature (page 5, lines 11-13);
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (page 5, lines 11-13); and
- wherein said projections have heights (See figures).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohman et al. (WO 3103835).

Regarding claims 2 and 4, Ohman et al. disclose all of the limitations as set forth above.

Ohman et al. do not teach: wherein said at least one flow path is two or more flow paths; said at least one sink is two or more sinks; and each flow path is connected to a sink of said two or more sinks.

However the structure of claim 2 is not different from having two devices of claim 1. (Unless applicant meant the multiple flow paths are connected to one of the multiple sinks and other sinks have no connections to any flow path.)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have two pathways connected to two different sinks. A mere duplication of parts has no patentable significance, since it involves only routine skill in the art.

Regarding claims 2 and 4, recitations directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art.

### ***Response to Arguments***

13. Applicant's arguments filed 5/27/09 have been fully considered.

14. The 112(2) rejections of claims 11 and 17 are withdrawn. The 101 rejection of claim 17 is also withdrawn.



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15. Amended claim 17 is now grouped with Group II and is withdrawn from further consideration (See paragraphs 2 and 3 of last office action. The amended claim 1 still is not applicant's contribution over prior art.).

16. Applicant's arguments with respect to the prior art rejection have been fully considered but they are not persuasive. (Also see paragraph 4 and bullets 4 of paragraphs 6, 7 and 8.) The microfluidic devices with vertical projections of Bhullar et al. and Regnier et al. are more than capable of causing a capillary flow of a fluid through the flow paths defined by the projections. It is the surface tension (the surfaces of the projections and the surface of the substrate) that overcomes the intermolecular forces, which pulls/moves the fluid.

The capillary action does not have to occur in capillary tubes, just as the wicking does not have to happen in/with a wick. It is a general phenomenon that is exemplified and named after the movement of a fluid in capillary tubes.

The effective U.S. filing date of the instant application is 5/26/2005. Therefore Ohman et al. is of a 102(b) reference against the instant claims.

### ***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

7/21/09

/Brian R Gordon/

Primary Examiner, Art Unit 1797